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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Etodolac Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for oral veterinary prescription use of etodolac tablets for the management of pain and inflammation associated with osteoarthritis in dogs.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1618.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, A Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501, filed NADA 141–108 that provides for oral veterinary prescription use of Etogesic™ (etodolac) tablets for the management of pain and inflammation associated with osteoarthritis in dogs. The NADA is approved as of July 22, 1998, and the regulations are amended by adding 21 CFR 520.870 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under 21 U.S.C. 360b(c)(2)(F)(i), this approval qualifies for 5 years of marketing exclusivity beginning July 22, 1998, because no active ingredient of the drug, including any ester or salt of the active ingredient, has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.870 is added to read as follows:

§ 520.870 Etodolac.

(a) *Specifications.* Each tablet contains 150 or 300 milligrams (mg) of etodolac.

(b) *Sponsor.* See 053501 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 10 to 15 mg per kilogram (4.5 to 6.8 mg/pound) of body weight per day.

(ii) *Indications for use.* For the management of pain and inflammation associated with osteoarthritis in dogs.

(iii) *Limitations.* Use once-a-day. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: 8/27/98
August 27, 1998

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Stephen F. Sundlof
Director, Center for Veterinary Medicine

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